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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/039,260	03/16/1998	A.K. GUNNAR ABERG	4821-306	9369

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EXAMINER	
CHANG, CELIA C	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/039,260	ABERG ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48,70 and 71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48,70 and 71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This is a RCE of SN 09/039,260.

The claims filed by applicants in an after final amendment have been entered per applicants' request.

Claims 1-47, 49-69 have been canceled.

Claims 48, 70 and 71 are pending.

2. Applicant's arguments with respect to claims 48, 70, 71 have been considered but are moot in view of the new grounds of rejection.

3. Claims 48, 70 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is the scope of claim 48 and 71 because the claims are drawn to solid pharmaceutical composition comprising 5 mg without any specification of 5 mg in what, i.e. 5 mg per gram of carrier? 5 mg per tablet? 5 mg each intake? etc. In absence of particularly pointing out what the ratio or quantitative relationship, the term comprising 5 mg does not offer any definition of the scope of the claims. In addition, the term "adapted for administration in a single dose per day" lacks antecedent basis in the specification.

4. Claims 48, 70 and 71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The specification lacks antecedent basis for the scope of solid pharmaceutical composition comprises 5 mg, or "adapted for administration in a single dose per day".

A survey of the specification indicated the following:

On page 14, lines 27-28 it was described "*The term "therapeutically effective amount of DCL or a pharmaceutically acceptable salt thereof" is encompassed by the above described dosage amounts*"

On page 14, lines 10-17, it was described "*In general, the total daily dose range for the conditions described herein is from about* ***0.1 mg to thess than about 10 mg*** *administered in single or divided doses orally, topically, transdermally or locally by inhalation. For example, a preferred oral daily dose range should be about* ***0.1 mg to about 5 mg****. A more preferred oral dose is about* ***0.2 mg to about 1 mg****.*

On page 28, examples 7-9 disclosed unit dosage capsules, soft gelatin capsules and tablets containing ***dosage unit*** *of 0.1 to 10 milligram.*

In view of the above disclosure, it was clear that the preferred range and the unit dosage range does not contain any single dosage description nor any single dosage per day description. In the description above nowhere can the one single dose of 5 mg as a single effective dose or in a unit dosage composition was found. As a matter of fact from the more preferred oral dose as disclosed on page 14, line 17, the narrower range is 0.2 mg to 1 mg which would not provide a "blaze mark" on 5 mg since it is at the high end of the preferred range. As set forth by the decision remarked by applicants in Fujikawa v Wattanasin, the Examiner has looked for blaze marks which single out particular trees but failed to see any.

4. Claims 48, 70 and 71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In view of the well recognized pharmacokinetic understanding in drug dosage regimens (see Notari et al. p.163-164), the specification as delineated supra would be considered guiding one skilled in the art to use multiple dosage units of the most preferred oral dose composition in units *about* ***0.2 mg to about 1 mg*** to achieve the required *daily dose range which should be about* ***0.1 mg to about 5 mg*** (the preferred oral

dose range) which would be a teaching away from the instantly limitation of single dosage of 5 mg per unit dose. No where in the specification provided enablement for a single unit oral dosage form in 5 mg per unit dose with efficacy in maintaining serum concentration as required by the above range of therapeutic values. Nor was there any "daily" single dose being enabled.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 48 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Villani et al. US 4,659,716 (1449 of record).

Determination of the scope and content of the prior art (MPEP §2141.01)

Vallani et al. '716 disclosed pharmaceutical composition comprising descarboethoxyloratadine, see col. 22-25. More specifically, preferred ranges and dosages of administration was explicitly described at col. 11 lines 29-33. The unit dosage for divided administration can be found to 5-100 mg/day in two to four divided doses or more preferably, 10-20 mg/day in two to four divided doses. Thus the preferred dosage units for the twice a day administration would be 2.5-50 mg or 5-10 mg units. While the dosage units in a smaller four dosage regimen be 1.25-25 mg per unit dose or 2.5-5 mg per unit dose.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The only difference between the instant claims and the prior art explicit description is that a single dose in 5 mg to be administered daily was not disclosed by the prior art.

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art in possession of the Vallani '716 reference would be in possession of the claimed invention because a unit dosage of 5 mg was clearly included in the most preferred range a 2.5-5 mg or 5-10 mg per unit and the total daily dosage of 5 mg per day was included in such dosage regimen and units description. In absence of unexpected result or explicit disclosure of the instant application that a single 5 mg unit dosage for once a day administration, there is nothing unexpected about the unit of 5 mg per dose or 5 mg per day which have been clearly included and recommended by the prior art.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
May 2, 2006

Celia Chang
Primary Examiner
Art Unit 1625